

REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. No claim is allowed. Claims 1-9, 14-18, and 21-25 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1-5 have been rejected under 35 U.S.C. §102(b) as being anticipated by Grigoriadis et al., J. Cell Biol. 106:2139-2151 (1998). The examiner states that Grigoriadis teaches a mesenchymal cell line which can differentiate into diverse cell types and factors which cause such differentiation. The examiner asserts that the reference anticipates the claimed subject matter by stating that the source of the cells may be relevant but it however does not appear to the examiner that the cells *per se* are different despite the differences in source. It is the examiner's position that although the instant cell line is defined as being "derived from a normal adult, the application does not demonstrate any difference between the cell line claimed and that disclosed in the prior nor does it provide evidence to refute the holding of anticipation. This rejection is respectfully traversed.

Unfortunately, applicants are unable to conduct side by side comparative tests with the cell line of Grigoriadis.

However, applicant emphasizes that the source of the cells, adult vs. fetus, is quite relevant and distinguishes the present claims from Grigoriadis. What may be present in the fetus may not be present in the adult as an organism ages. The Board of Appeals (1966) held in *Ex parte Cyba* 155 USPQ 757 that "In order that a rejection based upon inherency may be sustained such inherency must be certain. Clearly, there is no certainty that the presently claimed cell derived from a normal adult animal is present in a fetus; rather, it is only speculated. Furthermore, the present specification at page 9 defines the term "normal adult" as excluding embryo-derived cells, tumor cells and neonate animal-derived cells. Accordingly, Grigoriadis cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-9, and 14-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Grigoriadis et al. The examiner states that Grigoriadis teaches a mesenchymal cell line which can differentiate into diverse cell types and factors which cause such differentiation. The examiner asserts that it would have been obvious at the time the invention was made to use the cells of Grigoriadis in an assay for compounds which would cause the differentiation of the cells and putting the cells in a kit to run said assay. The

examiner concludes that the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary. This rejection is respectfully traversed.

The present invention is patentable for the reason that cells derived from a "normal adult" are different from cells from a fetus as discussed above in the \$102(b) anticipation rejection. As evidence that the presently claimed cell line derived from an adult animal is different from an embryonic or fetal cell line, since applicants are unable to perform a side-by-side comparative test, attached hereto is a declaration executed by the inventor Hidetomo KITAMURA which shows that the preferred CL-1 cell line (FERM BP-5823) according to the present invention differentiates to chondrocytes (cartilage formation) in the presence of Compound A, a chondrogenic promoter, in contrast to the ATDC5 embryonic carcinoma cell line widely used in the art as a chondrocyte precursor for studying chondrocyte differentiation. Compound A is a chondrogenic compound disclosed on page 17 of EP1156037 A1, a copy of which is attached hereto. Atsumi et al., Cell Diff. Develop. 30:109-116 (1990), and Takeichi et al., Develop. Biol. 87:340-350 (1981), copies of which are also attached hereto, describe the ATDC5 cell line.

Applicant is preparing a second declaration for filing in a Supplemental Response. In the event that this

second declaration is not matched up with the file of record, the examiner is requested to call the undersigned and a copy of the Supplemental Response with the second declaration will be handcarried or faxed to the examiner.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By



Allen C. Yun
Registration No. 37,971

ACY:pp
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\Y\YUAS\kitamura1\pto\amendmentB.doc